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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,770	09/19/2003	Pankaj Jay Pasricha	D6475	6393

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EXAMINER
KIM, JENNIFER M

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
01/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,770	PASRICHA, PANKAJ JAY	
	Examiner	Art Unit	
	JENNIFER MYONG M. KIM	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *7-9 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed October 31, 2008 have been received and entered into the application.

Action Summary

The rejection of claims 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiesi et al. (WO 00/06132A2) evidenced by Basu et al. (U.S.2002/0025348A1) is being **maintained** for the reasons stated in the previous Office Action.

The rejection of claims 1-6 and 15 under 35 U.S.C. 103(a) as being unpatentable over Chiesi et al. (WO 00/06132A2) in view of Basu et al. (U.S.2002/0025348A1) is being **maintained** for the reasons stated in the previous Office Action.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiesi et al. (WO 00/06132A2) evidenced by Basu et al. (U.S.2002/0025348A1) of record.

Chiesi et al. teach that pharmaceutical formulation for the treatment of inflammatory bowel disease containing as an active ingredient, beclomethasone dipropionate (BDP). (abstract). Chiesi et al. teach that the formulation demonstrates no systemic absorption of BDP and its major active metabolites. (page 14, Example 5). Chiesi et al. teach the amount of BDP to be employed includes 3mg and 5mg. (page 3, lines 9-11 and page 8-9 Examples 1 and 2).

Basu et al. report that IBS (irritable bowel syndrome) also tends to occur in IBD (inflammatory bowel disease) patients who are in remission from their IBD symptomologies. (page 1, [0009], last full sentence).

Accordingly, claim 10 drawn to "a method of **alleviating the symptoms of irritable bowel syndrome in an individual in need of such treatment**" is anticipated by the prior art as evidenced by Basu et al. because Basu et al. report that IBS tends to occur in IBD patients who are in remission from their IBD symptomologies. Therefore, the IBD patients disclosed by **Chiesi et al. are the patients in need of treatment of irritable bowel syndrome** because IBS tends to occur in IBD patients. Further, the mechanism of action of increasing the threshold of pain to colorectal distention, thereby alleviating the symptoms of irritable bowel syndrome in the individual would be inherent in Chiesi's method of treating inflammatory bowel disease comprising identical patients having IBD who are in need of alleviating the symptoms of irritable bowel syndrome as evidenced by Basu et al.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiesi et al. (WO 00/06132A2) in view of Basu et al. (U.S.2002/0025348A1) of record.

Chiesi et al. teach that pharmaceutical formulation for the treatment of inflammatory bowel disease containing an active ingredient, beclomethasone dipropionate (BDP). (abstract). Chiesi et al. teach that the formulation demonstrate no systemic absorption of BDP and its major active metabolites. (page 14, Example 5). Chiesi et al. teach the amount of BDP to be employed includes 3mg and 5mg. (page 3, lines 9-11 and page 8-9 Examples 1 and 2).

Basu et al. teach that the pathogenesis of inflammatory bowel disease and related disorders such as irritable bowel syndrome involve inflammation. (page 2, [0014]). Basu et al. teach that acute enteric inflammation is symptoms generated in irritable bowel syndrome (page 2, [0015]). Basu et al. teach that reduction in inflammatory agents would significantly effect the treatment of inflammatory disease like irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD). (page 2, [0015]). Basu et al. teach that by treating inflammation, hyperalgesia potentate by the inflammatory factors would be prevented. (page 2-3, [0015]). Basu et al. report that inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS) are related.

(page 1, [0003]). Basu et al. report that IBS also tends to occur in IBD patients who are in remission from their IBD symptomologies. (page 1, [0009], last full sentence).

It would have been obvious to one of ordinary skill in the art to employ beclomethasone to an individual having irritable bowel syndrome (IBS) for the treatment of such disorder because beclomethasone is effective for the treatment of inflammatory bowel disorder related to inflammation and because irritable bowel syndrome is an inflammatory disorder as taught by Base et al. One would have been motivated to make such modification in order to achieve an expected anti-inflammatory effect of beclomethasone to halt inflammation process generated as a symptom of irritable bowel syndrome. It is noted that 5mg amount employed by Chiesi et al. is within the mg/kg recited in claims 6 and 15 when the subject to be treated weigh 50kg. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

Response to Arguments

Applicant's arguments filed October 31, 2008 have been carefully considered but they are not persuasive. Applicant argues that a person having ordinary skill in this art would readily recognize that IBS and IBD are separate and unlinked disorders in view of Quigley (2005), the NIH websites and CCFA website. However, this argument will not be addressed because the references which relies upon is not on record. Applicant

essentially argues that irritable bowel syndrome (IBS) and IBD are distinct disorders. However, it is the Examiner's position that although, the histopathological changes may be different, it still does not change the relevant teaching of the prior art (Basu et al.) that IBS and IBD are inflammatory disease that is treatable with anti-inflammatory agents that halt an inflammatory process. In this case there is a great overlap in the population to be treated "patient in need thereof" because IBD patients disclosed by Chiesi et al. are the individuals in “need” of treating symptoms of irritable bowel syndrome as evidenced by Basu et al. who teach that IBS tends to occur in IBD patients. Applicant argues that the NIH website teaches that there is no link between irritable bowel syndrome and inflammatory bowel disease. However, this argument will not be addressed because the reference which relies upon is not on record. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/
Primary Examiner, Art Unit 1617

Jmk
January 16, 2009